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UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN JOSE DIVISION

UNITED STATES OF AMERICA,  
  
Plaintiff,  
  
v.  
  
ELIZABETH HOLMES and RAMESH  
"SUNNY" BALWANI,  
  
Defendants.

) Case No. 18-CR-258 EJD

)  
) DECLARATION OF AUSA ROBERT S. LEACH  
) IN SUPPORT OF UNITED STATES' MOTION TO  
) EXTEND DEADLINE BY WHICH TO COMPLY  
) WITH COURT'S NOVEMBER 5, 2019, ORDER

) Date: January 13, 2020  
) Time: 10 a.m.  
) Courtroom: 4, 5th Floor  
)  
)

1 I, Robert S. Leach, declare as follows:

2 1. I am an Assistant United States Attorney with the United States Attorney's Office for the  
3 Northern District of California. I am assigned to the prosecution of *United States v. Elizabeth Holmes &*  
4 *Ramesh "Sunny" Balwani*, Case No. CR 18-258 EJD. I make this declaration in support of the United  
5 States' Motion to Extend Deadline by Which to Comply with Court's November 5, 2019, Order.

6 2. Since November 5, the government has worked diligently to produce documents in  
7 response to the Court's November 5, 2019 Order.

8 3. On or about November 8, 2019, in conformance with the Court's Order, I met and  
9 conferred telephonically with counsel for defendants Holmes and Balwani about the search terms FDA  
10 was to use to search for and collect potentially responsive documents. Later that day, counsel for the  
11 defense emailed me stating "our position is that all custodian files should be electronically searched  
12 using the initial search terms in your email yesterday and the below additional search terms (non case  
13 sensitive): 'Theranos,' or 'LDT,' or 'Laboratory Developed Test,' or 'Laboratory-Developed Test,' or  
14 'Lab-developed test,' or 'nanotainer,' or 'fingerstick,' or 'finger stick,' or 'finger-stick' or 'Holmes.'" The  
15 "initial search terms in your email yesterday" were terms that FDA had previously advised had been  
16 used to collect for certain custodians: Balwani OR "Elizabeth w/3 Holmes" OR eholmes OR  
17 eholmes2003 OR eholmes@theranos.com OR Theranos OR "TSPU" OR "TSCD" OR Nanotainer OR  
18 "Capillary Tubes" OR "Nanotainer Tubes" OR "Lithium-Heparin" OR "CTN" OR "K2EDTA" OR  
19 "K152647" OR "K152965" OR "K152971" OR "Q151162" OR "Q151964" OR "Q160388" OR  
20 "Q160470" OR "K143236" OR "CW150009" OR "TLAS". I refer to all of the aforementioned terms  
21 above collectively as "Collection Terms".

22 4. On November 19, 2019, I traveled to the East Coast to meet with FDA and CMS  
23 representatives about a plan for production of documents in response to the Court's November 5, 2019  
24 Order. On November 20, 2019, I traveled to Baltimore to personally review potentially responsive CMS  
25 documents. On November 21, 2019, AUSA Jeff Schenk and I met in Washington, DC with the Deputy  
26 General Counsel and another attorney from CMS to discuss a plan for production of CMS documents. I  
27 anticipate the government will complete its production of CMS documents in response to the motion to  
28

1 compel on the deadline of December 31, 2019. On November 22, 2019, AUSA Schenk and I travelled  
2 to Silver Spring, Maryland, and met personally with approximately six FDA representatives to discuss a  
3 plan for the FDA's production.

4 5. On November 22, 2019, AUSA Schenk and I met and conferred telephonically further  
5 with the defense. The government proposed a plan that would address issues of redaction and  
6 duplication that generated objections to prior productions. The government proposed that FDA be  
7 ordered to produce documents responsive to the Collection Terms ("Ordered FDA Documents") to DOJ  
8 without any review for trade secret, confidential commercial information, or privileged information,  
9 notwithstanding certain statutory and regulatory prohibitions on FDA doing so. The government further  
10 proposed that it would produce documents responsive to the six categories to defendants without a  
11 specific review for trade secret, confidential commercial information, or privileged information, subject  
12 to an additional protective order providing for "attorney's eyes only" protection and later redaction for  
13 documents produced to defendants with trade secret and confidential commercial information. The  
14 government also requested that the defense identify the custodians it viewed as most significant, so the  
15 government could prioritize those custodians.

16 6. On November 27, 2019, counsel for defendant Balwani identified 22 lay custodians, in  
17 addition to the FDA-Criminal Investigation case agent, George Scavdis, assigned to the matter, as  
18 custodians the government should prioritize. Counsel for defendant Balwani also identified an  
19 additional 55 custodians to be searched.

20 7. On December 6, 2019, FDA produced to DOJ approximately 2.589 GB of Outlook 365  
21 email data from three custodians: J.K., L. Ll., and K.W. The government completed a review of this  
22 material for responsiveness to the six categories on December 18 and anticipates producing  
23 approximately 2,719 documents on December 31.

24 8. On December 19, 2019, FDA produced to DOJ approximately 91.37 GB of Outlook 365  
25 email data from twelve additional custodians (11 of whom were identified by defendant Balwani as a  
26 priority): J.F., C.L., I.P., J.S., J.D., K.S., K.K., K.H., M.C., S.M., U.S., and Y.C. Based on its review to  
27 date, the government anticipates producing approximately 136,092 documents on December 31.



1           9.       The government anticipates that on January 3, 2020, it will receive from FDA up to  
2 350GB of Outlook 365 email data from up to 12 custodians. The government is making arrangements to  
3 have that volume reviewed for a further production to the defense by the week of January 13, 2019.

4           10.      Since November 5, I have exchanged at least 100 emails and participated in at least a  
5 dozen phone calls with FDA counsel in an effort to achieve compliance with the Court's order. I have  
6 continually offered resources and assistance to FDA to accelerate the process, including, for example,  
7 additional personnel and/or funds.

8           11.      Based on my extensive dialogue with counsel for FDA, I understand there are substantial  
9 technological and other limits on FDA's ability to quickly collect documents from its custodians that  
10 additional personnel or funds will not address. I am advised that, in addition to hardware and software  
11 processing limitations that allow FDA to process one custodian a day, at best, FDA has contractual  
12 limits with its email and digital investigations software providers that cap how much data can be  
13 extracted simultaneously. I am advised that FDA is in the process of addressing these caps. I am  
14 advised that the process of restoring archived data of former employees is even more time consuming. I  
15 am also advised that FDA is devoting virtually all available Office of Chief Counsel eDiscovery and  
16 information technology resources to collecting documents for this matter, notwithstanding demands  
17 from other pending cases, and is requesting additional resources from other parts of FDA beyond the  
18 Office of Chief Counsel.

19           12.      For these reasons, the government is unable to meet the December 31, 2019, deadline set  
20 by the Court. The government has consulted at the highest levels of FDA about when it can complete its  
21 collection and delivery to DOJ. As describe above, defendant Balwani has identified 77 custodians  
22 (excluding the case agent). Defendant Holmes and FDA have identified an additional 11 for a total of  
23 88. In the interest of speed, FDA is implementing a tiered-approach where it collects electronically via  
24 remote collection Outlook 365 emails for current FDA personnel, electronic documents for current FDA  
25 custodians from network drives, documents from stand-alone devices, and documents from FDA  
26 databases, as well as hard copy documents from FDA personnel and archived documents from former  
27 FDA personnel. FDA is providing data to DOJ on a rolling basis and currently expects, using its best  
28

efforts, that it can provide all collected data to DOJ by April 30, 2020. This time table assumes FDA will conduct a manual search for approximately 23 custodians; i.e., under the supervision of FDA attorneys, 23 custodians will self-collect documents. Those custodians are: Almogela, D., *Amatrudo, V., Busch, M., Corbin, A., Dickenson, E., Drzewiecki, K., Hwang, L., Ju, R., Kolonay, J., Lloyd, L., Lubert, R., Mednick, D., Pennington, C., Rao, P., Rogers, M., Schaefer, K., Seeley, A., Smith, J., Sullivan, A., Vicente, W., Walburger, M., and Zuckerman, C.* The custodians listed in italics are attorneys in FDA's Office of Chief Counsel. I believe attorneys in FDA's Office of Chief Counsel by virtue of training and experience are capable of following specific instructions for the search; I am advised many have done so in prior cases.

13. The government had Agent Scadvis self-collect documents from his devices. Agent Scadvis had no involvement with Theranos prior to the criminal investigation. He had no reason to possess documents responsive to the six categories, other than documents he created or received during the investigation. Given his involvement in the criminal investigation, he is fully capable of manually searching his files for responsive information under the supervision of the prosecutors on this matter.

14. Attached as Exhibit A are portions of the transcript from the November 4, 2019 hearing on the motion to compel.

I declare, under penalty of perjury, that the foregoing is true and correct. Executed this \_\_\_ day of December 2019.

ROBERT S. LEACH  
Assistant United States Attorney

**EXHIBIT A**

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN JOSE DIVISION

UNITED STATES OF AMERICA, ) CR-18-00258-EJD  
)  
PLAINTIFF, )  
) SAN JOSE, CALIFORNIA  
VS. )  
) NOVEMBER 4, 2019  
ELIZABETH A. HOLMES AND RAMESH )  
SUNNY BALWANI, ) PAGES 1 - 92  
)  
DEFENDANTS. )  
\_\_\_\_\_ )

TRANSCRIPT OF PROCEEDINGS  
BEFORE THE HONORABLE EDWARD J. DAVILA  
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF: UNITED STATES ATTORNEY'S OFFICE  
BY: JOHN C. BOSTIC  
JEFFREY B. SCHENK  
150 ALMADEN BOULEVARD, SUITE 900  
SAN JOSE, CALIFORNIA 95113  
  
BY: ROBERT S. LEACH  
1301 CLAY STREET, SUITE 340S  
OAKLAND, CALIFORNIA 94612

(APPEARANCES CONTINUED ON THE NEXT PAGE.)

OFFICIAL COURT REPORTER:

IRENE L. RODRIGUEZ, CSR, RMR, CRR  
CERTIFICATE NUMBER 8074

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY  
TRANSCRIPT PRODUCED WITH COMPUTER



11:27AM 1 TO THOSE TERMS.

11:27AM 2 IT'S DIFFICULT FOR ME TO ESTIMATE AT THIS POINT WITHOUT  
11:27AM 3 KNOWING THE VOLUME, BUT I DO THINK THAT IF THE COURT WERE TO  
11:27AM 4 ORDER THE PRODUCTION BY THE END OF THE YEAR, WE WOULD DO OUR  
11:27AM 5 ABSOLUTE BEST AS WE HAVE BEEN DOING TO MAKE THAT DEADLINE.

11:27AM 6 THE COURT: OKAY.

11:27AM 7 MS. NORTON: YOUR HONOR, THIS IS MARCI NORTON.

11:27AM 8 I WOULD JUST LIKE TO ADD THAT THERE'S ANOTHER QUESTION  
11:27AM 9 HERE, WHICH IS IF WE HAD TO GO BACK TO OUR ORIGINAL SEARCH OF  
11:27AM 10 THE OVER 80 CUSTODIANS THAT HAVE BEEN SEARCHED SO FAR AND ADD  
11:27AM 11 NEW SEARCH TERMS LIKE FINGERSTICK OR LTD, THAT WOULD TAKE QUITE  
11:27AM 12 SOME TIME BECAUSE FOR THE FORMER EMPLOYEES THOSE SEARCHES ARE  
11:27AM 13 OUT OF OUR HANDS. THOSE ARE DONE BY OUR OFFICE OF INFORMATION  
11:27AM 14 MANAGEMENT STAFF, AND I THINK WE WERE RECENTLY TOLD THAT IT'S  
11:28AM 15 AT LEAST SIX WEEKS TO DO A SEARCH OF A FORMER EMPLOYEE'S FILES.

11:28AM 16 SO WHAT MS. MARTINEZ-RESLY WAS TALKING ABOUT IS IF WE ADD  
11:28AM 17 THOSE SEARCH TERMS TO THE CURRENTLY COLLECTED DOCUMENTS, WHICH  
11:28AM 18 I BELIEVE IS HUNDREDS OF THOUSANDS OF PAGES, THAT COULD BE DONE  
11:28AM 19 WITH THE SOFTWARE THAT WE HAVE NOW.

11:28AM 20 IF WE'RE TALKING ABOUT RESEARCHING, ESPECIALLY WITH  
11:28AM 21 RESPECT TO THOSE FORMER EMPLOYEES, I DON'T KNOW THAT WE WOULD  
11:28AM 22 BE ABLE TO MEET AN END-OF-THE-YEAR DEADLINE.

11:28AM 23 THE COURT: OKAY. THANK YOU. MR. COPPERSMITH.

11:28AM 24 MR. COOPERSMITH: YOUR HONOR, JUST TO BRIEFLY POINT  
11:28AM 25 OUT IN RESPONSE TO ONE THING THAT WAS SAID, THIS IS IN NO WAY



CERTIFICATE OF REPORTER

I, THE UNDERSIGNED OFFICIAL COURT REPORTER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY

CERTIFY:

THAT THE FOREGOING TRANSCRIPT, CERTIFICATE INCLUSIVE, IS A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE ABOVE-ENTITLED MATTER.

A handwritten signature in black ink that reads "Irene Rodriguez". The signature is written in a cursive, flowing style with a large, decorative flourish at the end of the last name.

IRENE RODRIGUEZ, CSR, RMR, CRR  
CERTIFICATE NUMBER 8074

DATED: NOVEMBER 7, 2019